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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,025	01/29/2004	Jeffrey Marc Dayno	21311	4710
210	7590	06/15/2005	EXAMINER	
MERCK AND CO., INC			KIM, JENNIFER M	
P O BOX 2000			ART UNIT	
RAHWAY, NJ 07065-0907			PAPER NUMBER	

1617

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,025

Applicant(s)

DAYNO ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,7-10,15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,11-14,16,18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed March 28, 2005 have been received and entered into the application.

Action Summary

The rejection of claims 1, 2, 5, 6, 11-14, 16 and 18 under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (WO 02/089798A2) and Gallagher et al. (1987) are being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1, 2, 5, 6, 11-14, 16 and 18 under 35 U.S.C. 103(a) as being unpatentable over Smitchieva et al. (U.S.Patent No. 6,384,034 B2) and Gallagher et al. (1987) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicant's arguments filed March 28, 2005 have been fully considered but they are not persuasive. Applicants argue in the instant case, one of ordinary skill in the art with knowledge of Allen and Gallagher would in no way have been motivated to combine these two references to arrive at the present invention since there are numerous analgesic and anti-migraine medications known to the ordinary skill artisan to treat or prevent migraine and the Examiner has failed to sufficiently explain why the ordinary skilled artisan would select the claimed combination of a cyclooxygenase-2

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inhibitor and beta blocker out of the vast number of other possible combination therapies. This is not persuasive because the motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)). It is clear from the cited reference Allen et al. that etoricoxib is administered at a dosage range from 10mg to about 200mg which is within Applicants' claimed effective range set forth in claim 6 is useful for treatment and prevention of migraines and it is clear from the cited reference Gallagher et al. that timolol maleate 10-30mg is effective in reducing frequency of common migraine headaches. Therefore, combination of etoricoxib and timolol maleate would treat migraine headaches as well. One of ordinary skill in the art would have been motivated to combine etoricoxib and timolol maleate in a single formulation with a reasonable expectation of successfully treating migraine with single convenient formulation. Applicants next argue that one having ordinary skill in the art with knowledge of Smitchieva would in no way be motivated to substitute timolol maleate for a 5-HT_{1B/1D} agonist based on the teachings of Gallagher and that the Examiner has failed to sufficiently explain why the ordinary skilled artisan would be motivated to select timolol out of the multitude of other antimigraine medications available and substitute timolol for the 5-HT_{1B/1D} agonist taught in Smitchieva. This is not persuasive because given the broadest interpretation of the claims drawn to "comprising" administering etoricoxib and timolol, it would have been obvious to one of ordinary in the art to combine timolol maleate to the etoricoxib comprising composition taught by Smitchieva et al. to achieve at least an additive effect

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in treatment of migraine. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above, the Office Action of December 29, 2004 is deemed proper and asserted with full force and effect herein to obviate applicants' claims. The rejections are restated below for the Applicants' convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 11-14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (WO 02/089798A2) and Gallagher et al. (1987).

Allen et al. teach COX-2 selective inhibitor, etoricoxib, is effective for the treatment of migraine. (abstract, page 2, lines 10-20). Allen et al. teach etoricoxib is administered at a dosage range from 10mg to about 200mg, which is within Applicants claimed effective range set forth in claim 6. (page 3, lines 1-3). Allen et al. teach etoricoxib may also be administered in combination with other agents for the treatment

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or prevention of migraines and such administration can be concomitantly. (page 8, lines 16-20).

Allen et al. do not teach the combination with a beta-adrenergic receptor blocking agent, timolol maleate and the dosage of timolol.

Gallagher et al. teach timolol maleate 10-30 mg is effective and has been shown to reduce the frequency of common migraine headaches. (abstract).

It would have been obvious to one of ordinary skill in the art to employ combinations of etoricoxib and timolol maleate for the treatment of migraine because all the components are well known individually for treating migraine. One would have been motivated to combine etoricoxib and timolol maleate for the treatment of migraine with a reasonable expectation of successfully treating migraine since Allen et al. teach that etoricoxib can be administered in combination with other agents concomitantly for the treatment or prevention of migraine. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPPA 1980)).

Claims 1, 2, 5, 6, 11-14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smitchieva et al. (U.S. Patent No. 6,384,034 B2) and Gallagher et al. (1987).

Smitchieva et al. teach a composition comprising MK-663 (etoricoxib) in effective amount of about 0.1 to 500mg/kg of body weight per day for the treatment of migraine. (abstract, column 3, line 5, column 4, lines 9-14, column 1, lines 37-50, claims).

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Smitchieva et al. do not teach the combination with a beta-adrenergic receptor blocking agent, timolol maleate and the dosage of timolol.

Gallagher et al. teach timolol maleate 10-30 mg is effective and has been shown to reduce the frequency of common migraine headaches. (abstract).

It would have been obvious to one of ordinary skill in the art to employ combinations of etoricoxib and timolol maleate for the treatment of migraine because all the components are well known individually for treating migraine. One would have been motivated to combine etoricoxib and timolol maleate for the treatment of migraine with a reasonable expectation of successfully treating migraine since Smitchieva et al. teach that etoricoxib can be administered in combination with other agents concomitantly for the treatment or prevention of migraine. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHEKJUN WANG
PRIMARY EXAMINER

Sreenivasan Padmanabhan
Supervisory Examiner
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Jmk

June 7, 2005


SHENGJUN WANG
PRIMARY EXAMINER